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Operational Requirements Document

AMC 001-00-B

Deployable Oxygen System (DOS)

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1. GENERAL DESCRIPTION OF OPERATIONAL CAPABILITIES.

a. Overall Mission Area. In accordance with AF Policy Directive 10-21, Air Mobility Command (AMC) is designated lead command for Aeromedical Evacuation (AE). As lead command, AMC provides evacuation of sick/injured patients, in peacetime and contingency operations, under the supervision of qualified medical crewmembers via fixed wing aircraft. The Air Force Medical Service (AFMS) mission includes provision of ground-based medical support for the full spectrum of medical care in deployed scenarios, including wartime operations, deterrence and contingency operations, peacetime engagement, crisis response, and Humanitarian Relief Operations. Air Combat Command (ACC) provides the Medical Equipment Force Package (MEFPAK) for this role. The AE and ground-based medical missions require medical support systems capable of providing therapeutic oxygen and operating oxygen-driven equipment in-flight and on the ground. The current methods employed to meet these requirements include use of the Portable Therapeutic Liquid Oxygen System (PTLOX) or high-pressure oxygen cylinders. The PTLOX is becoming logistically unsupportable. The advancement in the aircraft On-Board Oxygen Generation Systems (OBOGS) has significantly decreased the forward availability of Liquid Oxygen (LOX) resupply. The AFMS can no longer depend on line support for LOX and therefore must generate its own. The Deployable Oxygen System (DOS) program is supported under the USAF/SG Mission Need Statement (MNS), USAF 003-96, Aeromedical Evacuation Advanced Capability. AMC/SG's decision to retain use of the LOX storage vessel is based on insufficient power availability on most aircraft to operate gaseous oxygen generators with adequate capacity to meet mission requirements. More efficient LOX storage vessels would significantly reduce boil-off loss and improve mission capability. Additionally, AMC/SG desires its own portable LOX filling station to support use of the improved LOX storage vessel. The liquid oxygen generation portion of the DOS is intended to provide that capability, thus eliminating their current dependence on flight line supported LOX plants.

b. Type of System Proposed. The 311th HSW/YA has conducted aggressive market research to determine civilian sector capabilities and potential solutions. After conducting a literature review and discussions with industry, no single Commercial Off The Shelf (COTS) item exists that will support all DOS requirements. Technology limitations and aircraft power availability prevent a one-piece solution. Therefore, DOS is proposed as a system of systems comprising: (1) gaseous oxygen generator, (2) oxygen liquefier, and (3) liquid oxygen (LOX) storage vessel. Air Force Research Laboratory/HE completed a development effort in FY00, which demonstrated a minimized capability to generate, liquefy, store, and deliver medical grade oxygen. The gaseous oxygen generator and LOX storage vessel will supply a continuous flow of no less than 93 percent oxygen to meet user requirements. That portion of delivered gas, which is not oxygen, shall meet conditions stipulated in United States Pharmacopoeia (USP) for "Oxygen 93%". Additionally, the gaseous oxygen generators and LOX storage vessels will provide oxygen at prescribed flow rates and at pressures required to operate oxygen-driven equipment included in AFMS deployable medical assemblages. Gaseous oxygen generators and LOX storage vessels will have the capability to continue to operate and deliver uninterrupted oxygen flow at specified operating pressures during and after periods of power interruption.

c. Operational Concept. The DOS units will be included on various allowance standards for specific AE Unit Type Codes. Increment 2 of the Mobile Air Staging Facility (MASF) will require one full DOS, plus extra LOX storage vessels for the storage of LOX for AE missions. In addition, one to two more gaseous oxygen generators will be required to supply gaseous oxygen to patients in the 25 bed MASF. The DOS will work continuously to generate and liquefy oxygen based on patient and AE needs. Each in-flight medical kit will deploy with a minimum of two LOX storage vessels. Planning factors include a full DOS be located at strategic hubs, Patient Movement Item (PMI) Centers and Aeromedical Evacuation Squadron bed-down locations to ensure LOX storage vessel fill capability at various locations.

d. Support Concept. The Air Force Medical Logistics Office (AFMLO) will submit DOS to the Joint Readiness Clinical Advisory Board (JRCAB) for national stock listing approval. The supply support concept will be accomplished either organically or through Contractor Logistics Support (CLS). The depot level repair concept will be based on the Source of Repair Assignment Process (SORAP). Supportability Analysis will be conducted to ensure the design criteria and requirements are considered and incorporated into the product. The detailed logistics support concept will be documented in the DOS Logistics Management Information.

e. Mission Needs Statement. This Operational Requirements Document (ORD) is associated with a USAF/SG MNS 003-96; Aeromedical Evacuation Advanced Capability dated 30 Sept 97.

2. THREAT. The DOS is not likely to be a primary target, however, it is subject to collateral destruction and damage from conventional explosive weapons and munitions, as well as the effects of radio-electronic combat, high-altitude electromagnetic pulse (HEMP), and potential contamination and damage to electronic components caused by nuclear, biological, and chemical (NBC) effects.

3. SHORTCOMINGS OF EXISTING SYSTEMS

a. The PTLOX is becoming logistically unsupportable. The advancement in the aircraft OBOGS has significantly decreased the forward availability of LOX. The AFMS can no longer depend on line support for LOX and therefore must generate its own. The PTLOX, which has a capacity of 10 liters, continually vents gaseous oxygen and can be expected to vent a minimum of one liter of LOX per 24-hour period. PTLOX units in poor condition or those that have not received proper maintenance may vent up to five liters, or fifty percent of their LOX per 24-hour period. Support in deployed locations to maintain and fill PTLOX units is entirely dependent upon availability of LOX stores and appropriate aircraft maintenance personnel to service the PTLOX. Frequently, aeromedical evacuation staging locations and ground-based medical assemblages are located at forward operating bases, which do not possess aircraft maintenance activities. Due to these far-forward locations, liquid oxygen is generally unavailable at deployed locations, necessitating rotation of PTLOX units rearward for maintenance and filling. This requirement drastically decreases availability of the PTLOX for patient care and movement and increases the logistical tail required to support it.

b. Oxygen cylinders pose an assortment of operating and logistics difficulties. As a time-limited oxygen supply, the ability to deliver therapeutic oxygen is dependent upon their availability and the capability to return spent cylinders to a location where they can be maintained and refilled. High-pressure cylinders add excessive weight and volume to the airlift requirement and must be handled as hazardous cargo due to their high operating pressures (1800-2000 psi). Instability, lack of adequate securing mechanisms, and potential for catastrophic pressure valve failures if mishandled are further considerations.

4. CAPABILITIES REQUIRED.

a. System Performance. Threshold requirements are designated by **[T]** and the objective requirements are designated by **[O]**. An asterisk **[*]** denotes a key performance parameter.

(1) Key Performance Parameters (KPPs) [*].

Key Performance Parameters	Threshold and Objective
Oxygen Quality	Oxygen purity will be 93% **[T]**, 99% **[O]**. The balance of delivered contents shall meet the stipulations in USP.
Food and Drug Administration (FDA) Approval.	DOS will be approved by the FDA as a medical device in accordance with federal law.

(2) Common User Requirements. The DOS must be capable of providing reliable oxygen generation capability for extended periods of time in diverse global locations. To meet the multi-mission requirements of the AFMS's deployable medical systems, the DOS must be able to meet these requirements in both ground-based medical assemblages as well as multiple aeromedical evacuation platforms.

(a) Oxygen Quality. **[*]** Oxygen purity will be 93% **[T]**, 99% **[O]**. The balance of delivered contents shall meet the stipulations in USP.

(b) Oxygen Storage/Delivery: The Liquid Oxygen (LOX) storage vessel will have a capacity of 15 **[T]**, 25 **[O]** liters and be capable of delivering 66**[T]**, 80 **[O]** Liters Per Minute (LPM) of gaseous oxygen at 50 +/- 5 psig **[T]**. Flow rate and pressure will be maintained with as little as 1 liter of LOX remaining in the vessel. The LOX storage vessel will provide a minimum of six oxygen outlets **[T]**. Each outlet will be capable of flow rates of 0.5 to 15 LPM **[T]** and one outlet will be capable of providing up to 60LPM **[T]** or greater. Each outlet will be clearly labeled with the capability and LPM flow rate decal. Outlets will be compatible with standard oxygen hoses and flow meters. The new LOX storage vessel must interface with the liquefier and current flight line support. Manufacturer will provide a detachable accessory kit for each liquid oxygen (LOX) storage vessel for delivery/distribution of oxygen to patients. The accessory kit will include three standard medical grade oxygen hoses (20 feet minimum), flow regulators for each outlet and three medical grade, dry sterile oxygen humidification bottles. The accessory kit will be interoperable with the gaseous oxygen generator.

(c) Oxygen Generation/ Distribution (Gas): The gaseous oxygen generator will produce gaseous oxygen at a rate of 33 LPM via 3 outlets **[T]**, 45 LPM via 4 outlets **[O]** at 50 +/- 5psig. The gaseous oxygen generator will have the capability to fill D and E size oxygen cylinders using an integral high-pressure compressor. Each outlet will be capable of delivering flow rates of 0.5 to 15 LPM **[T]** and each outlet will be capable of total output of the system if feeding the liquefier or other high output medical device. Outlets will be compatible with standard oxygen hoses and flow meters. Manufacturer will provide an accessory kit for each gaseous oxygen generator for delivery/distribution of oxygen to patients. The kit will include standard medical grade oxygen hoses (20 feet minimum) and flow regulators for each outlet and will be interoperable with LOX storage vessel. The kit will be secured to gaseous oxygen generator. Gaseous oxygen generator shall have audible and visual alarms for low oxygen purity and low oxygen pressure **[T]**. The gaseous oxygen generator will have built-in-test (BIT) features, which provide the operator with fault indicators.

(d) Oxygen Generation (Liquid): The oxygen liquefier will generate liquid at a rate 1.4 **[T]**, 2.8 **[O]** liters per hour. The liquefier must interface with the gaseous oxygen generator and the new LOX storage vessel. The oxygen liquefier must be capable of filling the current PTLOX.

(e) Emergency Operation: In the event of power failure, the gaseous oxygen generator will be capable of supplying oxygen to patients for two hours. This system will be capable of filling and using D or E size cylinders for delivery in emergency situations **[T]**.

(f) Fit into Ambulances and Ambuses: The LOX storage vessel will fit in DOD rear-loading ambulances and ambuses without impeding the operational medical efficiency [T]. The capability to fit into DOD side-loading ambuses is desirable **[O]**.

(g) Fit into Tentage: The DOS will fit into the Alaskan shelter system and all Tent Extendable Modular Personnel (TEMPER) tents, to include the Chemically Hardened Air Transportable Hospital (CHATH). The DOS will fit through all openings and not pose any damage to flooring **[T]**.

(h) Fit into Fixed-and Rotary-Wing Aircraft: The DOS will fit through the various door openings on fixed-and rotary-wing aircraft for transport. The LOX storage/delivery vessel will fit and operate within the litter stanchion area of aeromedical fixed wing aircraft, without impeding egress, restricting routine aircrew operations, or taking up space in the aisles.

(i) Human Factors/Portability/Size. Each DOS component will be portable, allowing four person carry onto or into aeromedical evacuation aircraft, ambus, ambulance or tentage. Exception; LOX storage/delivery system will be portable, allowing two person carry onto or into aeromedical evacuation aircraft, ambus, ambulance or tentage. The gas oxygen generator system will not exceed 300 lbs **[T]**, 150 lbs **[O]**, the oxygen liquefier will not exceed 300 lbs **[T]**, 150 lbs **[O]** when filled to capacity, and the LOX storage vessel will not exceed 150 lbs **[T]**, 100 lbs **[O]** when filled to capacity. These weights will not include storage/shipping containers. The DOS will fit within the litter stanchion area **[T]**. The DOS total volume will not exceed 52 cubic

feet **[T]**. The DOS will be of modular design and will be easily assembled by medical crewmembers. Use of retractable and lockable wheels may be used for ease of transport, movement and maneuvering of the DOS components. **Deployment Response and Removal Times.** The DOS must meet the minimum deployment response and removal times within the specified number of people. Package A: Response available in 30 minutes, Teardown and removal in 30 minutes by ≤ 4 personnel **(T)**. Package B: Response available in 60 minutes, Teardown and removal in 60 minutes by ≤ 4 personnel: **(T)**. Package C: Response available in 20 minutes, Teardown and removal in 20 Minutes by ≤ 2 personnel **(T)**. In preparation for operational use the complete package A, B and C the DOS must be able to be set-up within 90 minutes. Minimize the footprint (volume and weight) of any wartime or contingency deployable part of the system, its training (ops and maintenance), and its support (spares, support equipment, technical data, manpower, etc). Reductions of the size and weight of the total of what we carry enroute and into battle reduces the burden on air transport, war fighters, and support resources.

(j) Vibration/Shock. The LOX storage vessel will operate during and after being subjected to rapid decompression, vibration, shock and acceleration as encountered during air, sea, and ground transportation. All other DOS components will operate after being subjected to vibration, shock and acceleration as encountered during air, sea, and ground transportation **[T]**.

(k) Humidity. The DOS must be capable of operation and storage in humidity levels of 0% to 100% Rh **[T]**.

(l) Temperature Operation Range. The DOS must be capable of operating in temperatures ranging from 32°F ± 7.2°F **[T]**, **-40**°F **[O]** to 120°F ± 3.6°F **[T]**.

(m) Temperature Storage Range. The DOS must be capable of operations after being stored in temperature ranges from -40°F to 140°F **[T]**.

(3) Aircraft Integration:

(a) Power Requirements. The DOS system does not require aircraft power. The LOX storage vessel will utilize a 9 Volt battery for capacity readings.

(b) Securing Method: The DOS will be capable of being secured to floor provisions during flight operations on the following aircraft C-5, C-9, C-17, CV-22, C-130, C-141, KC-10, KC-135. DOS will be compatible with a standard 463-L cargo pallet; D-rings and 5000 lbs cargo tie down straps. Securing the LOX storage vessel will be accomplished while wearing artic, chem/bio or flight gloves in a maximum time of 20 **[T]**, 10 **[O]** minutes.

(c) Food and Drug Administration (FDA) Approval. **[*]** DOS will be approved by the FDA as a medical device in accordance with federal law.

(d) Altitude. The DOS LOX storage/delivery system will operate at a cabin altitude up to 15,000 **[T]**, 25,000 **[O]** feet mean sea level (MSL).

(e) Decompression. The LOX storage vessel will operate safely during and after decompression from 8,000 ft to 45,000 ft cabin altitude at 1, 7, and 60-second intervals. All other components of the DOS, in their transport configuration, will operate safely after exposure to decompression from 8,000 ft to 45,000 ft cabin altitude at 1, 7, and 60-second intervals **[T]**.

(4) Bare Base Integration:

(a) Power Requirements. The DOS system will require electric power for operation and will be compatible with the Ground-Based Deployable Power Generation and Distribution System (DPGDS) at worldwide deployable locations. For compatibility with these power sources, the DOS will be designed for operation on 110-220 VAC, 50-60 Hz power input **[T]**.

(5) Storage Environment: The DOS will be capable of withstanding long-term storage in a facility that is not environmentally controlled. The storage configuration and packaging will provide the capability for periodic inspection, preventive maintenance, and corrective maintenance **[T]**.

(a) The DOS will be capable of being removed from long-term storage, set-up, and fully operational within 90 minutes **[T]**, 60 minutes **[O]**.

b. Information Exchange Requirements. Information Exchange Requirements. The DOS has no communication capabilities within the aircraft or while on the ground.

c. Logistics and Readiness. The DOS will have a minimum (storage/operational) life of 10 years, of which operational life will be 10 years **[T]**, 15 years **[O]**. The initial logistics concept for the DOS is contractor logistic support (CLS). System design will provide for ease and speed of maintenance and upgrade and minimize the logistics tail. System components will be easy to access and maintain. Removal, repair, replacement, adjustment, modification, checkout, and calibration will be accomplished using common shop tools. Any special tools will be kept to a minimum and, as necessary, delivered as part of the support package. Specific maintenance career fields (Biomedical, Electro-Environmental, Petroleum, Oils, and Lubricants (POL), contract support) will be determined when the specific maintenance concept has been identified.

(1) Reliability/Maintainability: The reliability of the DOS will be equal to or better than similar existing oxygen systems. The Mean Time Between Failure (MTBF) will be a minimum of 1080 hours. The DOS mean time to repair (MTTR) will be a maximum of 4 hours **[T]**, two hours **[O]**. Liquid and gaseous generators will be equipped with an internal usage clock to track hours of operation. Time critical items, as identified by the manufacturer, will be specifically tracked. Time change items, as identified by the manufacturer, will also be tracked. LOX storage vessel usage will be tracked based on calendar time.

d. Other System Characteristics.

(1) Electromagnetic Interference (EMI). The system must operate in its intended electromagnetic environment without causing or suffering any unacceptable performance

degradation due to electromagnetic interference to or from other equipment in same environment **[T]**.

(2) Environmental Concerns.

(a) The DOS will be able to operate during and after being exposed to harsh environmental conditions such as blowing sand, snow, sleet, dust, rain, and salt fog. The LOX storage vessel must also operate within aircraft bank and angle of attack restrictions **[T]**.

(b) If any component of DOS is operated in a closed environment; venting will be at a level to prevent an oxygen enriched (hazardous) atmosphere **[T]**.

(c) The DOS will be capable of withstanding bacterial and/or viral disinfection with standard hospital disinfectants and five percent bleach solution without degradation of structural components or performance. The DOS will be decontaminable to the same degree as all other medical equipment items **[T]**.

(d) When disposal of the DOS or its subsystems becomes necessary, the disposal process will not pose a threat to the environment. Environment, Safety, and Health (ESH) Operations, maintenance, support, and disposal require a solution with minimal hazardous materiel use and which minimizes ESH cost and risks. The proposed solution must not be in legal/regulatory conflict with environmental, safety, or health requirements (including reporting).

(3) Communications. The DOS has no communication capabilities or requirements.

(4) Security. The DOS has no security impacts.

(5) Conventional, Initial Nuclear Weapons Effects, Electromagnetic Environmental Effects (E3), and Nuclear, Biological, and Chemical Contamination Survivability (NBCCS), Conventional Effects. The DOS will be capable of performing under a wide range of potential battle-space environmental conditions and hazards (natural and manmade). It is desired that the DOS be recoverable after the effects of chemical and biological contamination **[O]**.

(6) Unplanned Stimuli. DOS shall not present a safety hazard to personnel, patients, facilities and aircraft when effected by bullets or conventional sympathetic detonations, while in operational or non-operational status **[O]**.

5. PROGRAM SUPPORT. The DOS will be covered by an initial warranty for 12 months **[T]**, 36 months **[O]** that will include all parts and labor required for repair and maintenance. The DOS will be designed to maximize operational availability by minimizing maintenance requirements. Joint Potential Designation is considered "Independent."

a. Maintenance Planning.

(1) Depot Repair. Interim contractor support shall be utilized until completion of the Source of Repair Approval Process (SORAP) determines the depot repair source and that capability are established. The depot repair concept will be based on SORAP.

(2) Technical Data. An integrated tech data package covering DOS storage, maintenance, inspection and integration will be delivered in digital format in accordance with Air Force Standards. Data delivered digitally will be on CD ROM and in commercial desktop publishing format. The format will be stored managed, and maintained in the Joint Computer Aided Acquisition and Logistics Support (JCALS) system. One paper copy of DOS commercial technical manuals (operation/maintenance manuals) will be provided per unit. Manuals will have the ability to be updated as required **[T]**.

(3) Logistics Management Information (LMI). LMI will be conducted to ensure the supportability design criteria and requirements are considered and incorporated into the design.

b. Support Equipment. Support equipment, special test or calibration equipment and procedures used to maintain the DOS will be documented in the operations and maintenance manual(s) to include troubleshooting. The maintenance concept will provide for the specified operational availability and capability at the lowest life-cycle cost. The detailed logistics support concept will be documented in the DOS Integrated Logistics Support Plan.

c. Human Systems Integration. The seven Human Systems Integration elements must be optimized for total system performance and reduce total operational cost. The seven elements are, manpower, personnel, training, human factors, safety, health hazards and survivability. The contractor will provide DOS operation, calibration, repair, and maintenance training, utilizing the "train-the-trainer" concept. Computer based learning programs will be used where feasible. The DOS will be developed with the goal of no increase in manpower requirements for the Air Force.

(1) DOS operational procedures will be simplistic in design, to allow one five-level technician to operate it with minimal supervision after initial training requirements have been met.

(2) Performance of calibration and maintenance requirements will not require a technician skill level above five.

(3) The DOS will be operable in any level of Mission-Oriented Protective Posture (MOPP) or cold weather clothing to include standard military issue gloves or mittens.

(4) DOS components and shipping containers will have at least four lift points installed to permit four personnel to carry. Exception; LOX storage vessel will have at least two lift points to permit two personnel to carry.

d. Computer Resources. N/A

e. Other Logistics Considerations. A logistics support/provisioning concept will be developed by the manufacturer for the system based on the system design, the operational concept, and the projected utilization of the system in addition to a recommended spare parts kit.

(1) Preservation, packaging, and packing will be to a degree of protection to preclude damage to containers and/or contents thereof under normal handling during air, sea, and land shipping conditions. Where possible, equipment will be packed in fully reusable, spun molded polyethylene plastic or equal fiberglass. The container(s) will be equipped with a cushioning and support system sufficient to protect the contents from damage in-transit and storage due to vibration, shock, or compression. Any hazardous materials associated with the DOS will be packaged to meet air, sea, and surface transportation safety packaging requirements. The design of the LOX storage vessel will provide protection from damage in shipping/handling, operating and storage conditions. All DOS components and integration points will be clearly marked with applicable percentage medical oxygen.

f. Command, Control, Communications, Computers, and Intelligence. N/A

g. Transportation and Basing. The DOS and its shipping storage container will be durable or self-contained for packaging on an open 463L pallet with other assets. System must be capable of worldwide transportation under normal air, sea, and land shipping conditions. All hazardous cargo protocols will be followed when transporting LOX. DOS will be deployable to worldwide locations with adequate power.

h. Standardization, Interoperability, and Commonality. The DOS will be deployable with ground-based or AE medical assemblage and operate from available power sources (ref: 4.(3).(a). and 4.(4).(a).

(1) The DOS has no communication interoperability issues.

(2) The DOS has no commonality issues.

i. Geospatial Information and Services Support. N/A

j. Environmental Support. N/A

6. FORCE STRUCTURE. The number of LOX storage vessels needed by the aeromedical evacuation community, including Air National Guard and Air Force Reserves units, is estimated at (503), which includes two per aeromedical evacuation in-flight medical kit (400) and four for each mobile aeromedical staging facility (100). The number of oxygen liquefiers and gaseous oxygen generators needed to support aeromedical evacuation assemblages is (62). The number of gaseous oxygen generators needed for Air Combat Command ground-based assemblages is estimated at (350). The number of oxygen liquefiers, gaseous oxygen generators and LOX storage vessels needed to support USAFSAM is (1 each). The number of oxygen liquefiers, gaseous oxygen generators and LOX storage vessels needed to support Tri-Service Biomedical Equipment Repair School is (1 each). The number of oxygen liquefiers, gaseous oxygen

generators and LOX storage vessels needed to support the Aeromedical Evacuation Contingency Operations Training (AECOT) sites is (1 each).

Assemblage	Gaseous Qty	Liquefier Qty	LOX Stor Qty*
USER	AMC/ACC	AMC	AMC
MASF/EMEDS	**25 / 350**	**25**	**100**
In-flight Kits			**400**
PMI Centers			
AECOT	**1**	**1**	**1**
WRM Hubs			
AE Units	**30**	**30**	
USAFSAM	**1**	**1**	**1**
Tri-Service BMET	**1**	**1**	**1**
TOTALS	**408**	**62**	**503**

7. SCHEDULE CONSIDERATIONS.

a Initial Operational Capability (IOC) is scheduled for FY04. IOC will be achieved when the system is fielded to the initial units and training base, unit personnel are trained, training base is established, and maintenance system is in place.

b Full Operational Capability (FOC) is scheduled for FY05. FOC will be achieved when the system is totally procured; the identified force structure is trained; and a maintenance system is in place.

MILESTONE	TARGET DATE
IOC	
LOX Storage Vessel	FY 03
Gaseous Oxygen Generator	FY 06
Oxygen Liquefier	FY 06
FOC	
LOX Storage Vessel	FY 05
Gaseous Oxygen Generator	FY 07
Oxygen Liquefier	FY 07

8. Program Affordability

8.1 Oxygen Storage/Delivery: The LOX storage vessel contract award is expected in FY01. Remaining milestones will be defined by the winning offeror(s) in their proposal and captured in their Integrated Master Plan (IMP) and Integrated Master Schedule (IMS). The content of the IMP and IMS will depend heavily on the contractor's proposed architecture and program approach. Development efforts for FY01/FY02 will focus on increased dewar size, increased user capacity, FDA approval, and airworthiness certification. Production will begin in FY03.

8.2 Oxygen Generation/Distribution (Gas and Liquid): Both gas and liquid generation/distribution systems will have a development contract award in FY03. This effort will be a full and open competition thus milestones, IMP, and IMS will depend heavily on the contractors' proposed architecture, program approach, and evolution of technology. The development effort will span FY03-FY05 with production running from FY05-FY07.

Table 8.1 DOS Projected Financial Plan ($M)

	FY01	FY02	FY03	FY04	FY05	FY06	FY07
RDT&E (3600)	2.4	0.8	4.9	7.0	4.0	1.0	0.1
Prod (3080)			2.9	2.9	6.0	6.2	2.9

Annex
A. Rationale Annex

REFERENCES

a. DOD Directive 5000.1, *The Defense Acquisition System*, 23 October 2000

b. DOD Regulation 5000.2-R, *Operation of the Defense Acquisition System*, 23 October 2000

c. CJCSI 3170.01A, *Requirements Generation System*, 10 August 1999

d. CJCSI 6212.01B, *Interoperability and Supportability of National Security Systems, and Information Technology Systems*, 8 May 2000

e. AFI 10-601, *Mission Needs and Operational Requirements Guidance and Procedures*, 13 August 1999

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GLOSSARY

ABBREVIATIONS AND ACRONYMS

ACC	Air Combat Command
AE	Aeromedical Evacuation
AFMLO	Air Force Medical Logistics Office
AFMS	Air Force Medical Service
AMC	Air Mobility Command
CHATH	Chemically Hardened Air Transportable Hospital
CLS	Contractor Logistics Support
COTS	Commercial Off the Shelf
DPGDS	Deployable Power Generation and Distribution System
EMI	Electromagnetic Interference
FOC	Full Operational Capability
HEMP	High-Altitude Electromagnetic Pulse
IOC	Initial Operational Capability
JRCAB	Joint Readiness Clinical Advisory Board

LSA	Logistics Support Analysis
LOX	Liquid Oxygen
MASF	Mobile Air Staging Facility
MEFPAK	Medical Equipment Force Package
MNS	Mission Need Statement
MOPP	Mission-Oriented Protective Posture
MSL	Mean Sea Level
MTBF	Mean Time Between Failure
MTTR	Mean Time to Repair
NBC	Nuclear, Biological, and Chemical
NBCCS	Nuclear, Biological, and Chemical Contamination Survivability
OBOGS	On-Board Generation Systems
ORD	Operational Requirements Document
PMI	Preventative Maintenance Inspection
POL	Petroleum, Oils, and Lubricants
PTLOX	Portable Therapeutic Liquid Oxygen System
SORAP	Source of Repair Assignment Process

TEMPER	Tent Expendable Modular Personnel
USP	United States Pharmacopeia
WRM	War Reserve Materiel

Appendixes:
A: References
B: Distribution List
C: List of ORD Support Analysis (N/A)
D: CRD(s)—ORD KPP/requirements cross walk/linkage (N/A)

Glossary:
Abbreviations and Acronyms

Tables:

B: Information Exchange Requirements Matrix (N/A)

RCM PART 1.

Requirements Correlation Matrix – Part 1
Deployable Oxygen System
As Of Date: 20 Apr 01

System Capabilities and Characteristics Parameters	ORD I/II	
	Threshold	**Objectives**
1. Oxygen Quality* (4a(2)(a))	Must provide oxygen at 93 percent concentration. The balance of delivered contents shall be as stipulated by USP "Oxygen 93 Percent."	Must provide oxygen at 99 percent concentration. The balance of delivered contents shall be argon or nitrogen, except for trace concentrations of other atmospheric gases, not exceeding percentage levels allowed in "Oxygen, USP."
2. Oxygen Storage/Delivery (4a(2)(b))	The Liquid Oxygen (LOX) storage vessel will have a capacity of 15 liters. The LOX storage vessel will be capable of delivering 66 LPM at 50 +/- 5 psig. This flow rate and pressure will be maintained with as little as 1 liter of LOX remaining in the vessel. The LOX storage vessel will provide a minimum of six oxygen outlets. Each outlet will be capable of flow rates of 0.5 to 15 LPM and one outlet will be capable of providing 60LPM or greater. Outlets will be compatible with standard oxygen hoses and flow meters.	The Liquid Oxygen (LOX) storage vessel will have a capacity of 25 liters. The LOX storage vessel will be capable of delivering 80 LPM of gaseous oxygen at 50 +/- 5 psig. This flow rate and pressure will be maintained with as little as 1 liter of LOX remaining in the vessel.
3. Oxygen Generation (Gas) (4a(2)(c))	The gaseous oxygen generator will produce gaseous oxygen at a rate of 33 LPM via 3 outlets at 50 +/- 5psig. The gaseous oxygen generator will have the capability to fill D and E size oxygen cylinders. Each outlet will be capable of delivering flow rates of 0.5 to 15 LPM and each outlet will be capable of total output of system if feeding the liquefier or other high output medical device. The oxygen concentrator shall have audible and visual alarms for low oxygen purity and low oxygen pressure. Outlets will be compatible with standard oxygen hoses and flow meters. Manufacturer will provide an accessory kit for each gaseous oxygen generator for delivery/distribution of oxygen to patients. The kit will include standard medical grade oxygen hoses (20 feet minimum) and flow regulators for each outlet and will be interoperable with LOX storage vessel. The kit will be secured to gaseous oxygen generator.	The gaseous oxygen generator will produce gaseous oxygen at a rate of 45 LPM via 4 outlets at 50 +/- 5psig.
4. Oxygen Generation (Liquid) (4a(2)(d))	The oxygen liquefier will generate liquid at a rate of 1.4 liters per hour. The liquefier must interface with the gaseous oxygen generator and the new LOX storage vessel. The oxygen liquefier must be capable of filling the current PTLOX.	The oxygen liquefier will generate liquid at a rate of 2.8 liters per hour.

System Capabilities and Characteristics Parameters	ORD I/II	
	Threshold	**Objectives**
5 Emergency Operation (4a(2)(e))	In the event of power failure, the gaseous oxygen generator will be capable of supplying oxygen to patients for two hours. This system will be capable of filling and using D or E size cylinders for delivery in emergency situations.	
6. Fit into Ambulances and Ambuses (4a(2)(f))	The LOX storage vessel will fit and operate in DOD rear-loading ambulances and ambuses without impeding the operational medical efficiency.	The capability to fit into DOD side-loading ambuses is desirable.
7. Fit into Tentage (4a(2)(g))	The DOS will fit into the Alaskan shelter system and all Tent Extendable Modular Personnel (TEMPER) tents, to include the Chemically Hardened Air Transportable Hospital (CHATH). The DOS will fit through all openings and not pose any damage to flooring.	
8. Fit into Fixed and Rotary wing aircraft (4a(2)(h))	The DOS will fit through the various door openings on fixed-and rotary-wing aircraft. The LOX storage/delivery vessel will fit and operate within the litter stanchion area of aeromedical aircraft, fixed wing, without impeding egress, restricting routine aircrew operations, or taking up space in the aisles.	

System Capabilities and Characteristics Parameters	ORD I/II	
	Threshold	**Objectives**
9. Human Factors/Portability (4a(2)(i))	Each DOS component will be portable, allowing four person carry onto or into aeromedical evacuation aircraft, ambus, ambulance or tentage. Exception; LOX storage vessel will be portable, allowing two person carry onto or into aeromedical evacuation aircraft, ambus, ambulance or tentage. The gaseous oxygen generator will not exceed 300 lbs. The oxygen liquefier will not exceed 300 lbs when filled to capacity. The LOX storage vessel will not exceed 150 lbs when filled to capacity. These weights will not include storage/shipping containers. The DOS will fit within the litter stanchion area. The DOS total volume will not exceed 52 cubic feet. The DOS will be of modular design and will be easily assembled by medical crewmembers. Use of retractable and lockable wheels may be used for ease of transport, movement and maneuvering of the DOS components. **Deployment Response and Removal Times.** The DOS must meet the minimum deployment response and removal times within the specified number of people. Package A: Response available in 30 minutes, teardown and removal in 30 minutes by ≤ 4 personnel. Package B: Response available in 60 minutes, teardown and removal in 60 minutes by ≤ 4 personnel. Package C: Response available in 20 minutes, Teardown and removal in 20 Minutes by ≤ 2 personnel. In preparation for operational use the complete package A, B and C the DOS must be able to be set-up within 90 minutes.	The gaseous oxygen generator will not exceed 150 lbs. The oxygen liquefier will not exceed 150 lbs when filled to capacity. The LOX storage vessel will not exceed 100 lbs when filled to capacity. These weights will not include storage/shipping containers. The DOS and its storage/shipping containers will fit within the following dimensional envelope: 95" in length, 23" in width, and 41" in height. The DOS will be of modular design and will be easily assembled by medical crewmembers. Use of retractable and lockable wheels may be used for ease of transport, movement and maneuvering of the DOS components..
10. Vibration/Shock (4a(2)(j))	The LOX storage vessel will operate during and after being subjected to rapid decompression, vibration, shock and acceleration as encountered during air, sea, and ground transportation. All other DOS components will operate after being subjected to vibration, shock and acceleration as encountered during air, sea, and ground transportation.	
11. Humidity (4a(2)(k))	Humidity. The DOS must be capable of operation and storage in humidity levels of 0% to 100% Rh	
12. Temperature Operation Range (4a(2)(l))	The DOS must be capable of operating in temperatures ranging from 32°F +/- 7.2°F to 120°F.	The DOS must be capable of operating in temperature of -40°F.
13. Temperature Storage Range (4a(2)(m))	The DOS must be capable of operations after being stored in temperature ranges from -40°F to 140°F.	

System Capabilities and Characteristics Parameters	ORD I/II	
	Threshold	**Objectives**
14. Power requirements (Aircraft) (4a(3)(a))	N/A	
15. Securing Method (4a(3)(b))	The DOS will be capable of being secured to floor provisions during flight operations on the following aircraft C-5, C-9, C-17, CV-22, C-130, C-141, KC-10, KC-135. DOS will be compatible with a standard 463-L cargo pallet; D-rings and 5000 lbs cargo tie down straps. Securing the LOX storage vessel will be accomplished while wearing artic, chem/bio or flight gloves in a maximum time of 20 minutes.	Securing the LOX storage vessel will be accomplished while wearing flight gloves in a maximum time of 10 minutes.
16. Food and Drug Administration (FDA) Approval* (4a(3)(c))	DOS will be approved by the FDA as a medical device in accordance with federal law.	
17. Altitude (4a(3)(d))	The DOS LOX storage/delivery system will operate at a cabin pressure up to 15,000 feet mean sea level (MSL).	The DOS LOX storage/delivery system will operate at a cabin altitude up to 25,000 feet mean sea level (MSL).
18. Decompression (4a(3)(e))	The LOX storage vessel will operate safely during and after decompression from 8,000 feet to 45,000 feet cabin altitude at 1, 7, and 60-second intervals. All other components of the DOS, in their transport configuration, will operate safely after exposure to decompression from 8,000 feet to 45,000 feet cabin altitude at 1, 7, and 60-second intervals.	
19. Power Requirements (Bare Base) (4a(4)(a))	The DOS components requiring electric power for operation will be compatible with the Ground-Based Deployable Power Generation and Distribution System (DPGDS) and with worldwide deployable locations. For compatibility with these power sources, the DOS will be designed for operation on 110-220 VAC, 50-60 Hz power input.	
20. Storage Environment (4a(5))	The DOS will be capable of withstanding long-term storage in a facility that is not environmentally controlled. The storage configuration and packaging will provide the capability for periodic inspection, preventive maintenance, and corrective maintenance. **4b(1)(a)** The DOS will be capable of being removed from long-term storage, set-up, and fully operational within 90 minutes.	**4b(1)(a).** The DOS will be capable of being removed from long-term storage, set-up, and fully operational within, 60 minutes.

System Capabilities and Characteristics Parameters	ORD I/II	
	Threshold	**Objectives**
21. Logistics and Readiness (4c)	The DOS will have a system life of any combination of an operational life of ten and a storage life of fifteen years. The initial logistics concept for the DOS is contractor logistic support (CLS). System design will provide for ease and speed of maintenance and upgrade and minimize the logistics tail. System components will be easy to access and maintain. Removal, repair, replacement, adjustment, modification, checkout, and calibration will be accomplished using common shop tools. Any special tools will be kept to a minimum and, as necessary, delivered as part of the support package. Specific maintenance career fields (Biomedical, Electro-Environmental, Petroleum, Oils, and Lubricants (POL), contract support) will be determined when the specific maintenance concept has been identified.	The DOS will have a system life of any combination of an operational life of fifteen years and a storage life of fifteen years.
22. Reliability/Maintainability (4c(1))	The reliability of the DOS will be equal to or better than similar existing oxygen systems. The Mean Time Between Failure (MTBF) will be 1080 hours. The DOS mean time to repair (MTTR) will be four hours. Liquid and Gaseous generators will be equipped with an internal usage clock to track hours of operation. Time critical items, as identified by the manufacturer, will be specifically tracked. Time change items, as identified by the manufacturer, will also be tracked. LOX storage vessel usage will be tracked based on calendar time.	The DOS mean time to repair (MTTR) will be two hours.
23. Electromagnetic Interference (4d(1))	Must operate in its intended electromagnetic environment without causing or suffering any unacceptable performance degradation due to electromagnetic interference to or from other equipment in same environment.	

System Capabilities and Characteristics Parameters	ORD I/II	
	Threshold	**Objectives**
24. Environmental Concerns (4d(2))	**4d(2)(a).** The DOS will be able to operate during and after being exposed to harsh environmental conditions such as blowing sand, snow, sleet, dust, rain, and salt fog. The LOX storage vessel must also operate within aircraft bank and angle of attack restrictions. **4d(2)(b).** If any component of DOS is operated in a closed environment; venting will be at a level to prevent an oxygen enriched (hazardous) environment. **4d(2)(c)).** The DOS will be capable of withstanding bacterial and/or viral disinfection with standard hospital disinfectants and five percent bleach solution without degradation of structural components or performance. The DOS will be decontaminable to the same degree as all other medical equipment items. **4d(2)(d).** When disposal of the DOS or its subsystems becomes necessary, the disposal process will not pose a threat to the environment. In accordance with DoD 5000.2R, part 4, paragraph 4.3.7, the program will incorporate environmental, safety and health planning throughout the program life cycle.	
25. Conventional, Initial Nuclear Weapons Effects, Electromagnetic Environmental Effects (E3), and Nuclear, Biological, and Chemical Contamination Survivability (NBCCS), Conventional Effects. (4d(5))		The DOS will be capable of performing under a wide range of potential battle-space environmental conditions and hazards (natural and manmade). It is desired that the DOS be recoverable after the effects of chemical and biological contamination. .
26. Unplanned Stimuli (4d(6))	.	DOS shall not present a safety hazard to personnel, patient, or facilities and aircraft when effected by bullets or conventional sympathetic detonations, while operational or non-operational
27. Program Support (5)	The DOS will be covered by an initial warranty for 12 months that will include all parts and labor required for repair and maintenance.	The DOS will be covered by an initial warranty for 36 months that will include all parts and labor required for repair and maintenance.

28. Program Support (5a(2))	An integrated tech data package covering DOS storage, maintenance, inspection and integration will be delivered in digital format in accordance with Air Force Standards. Data delivered digitally will be on CD ROM and in commercial desktop publishing format. The format will be stored managed, and maintained in the Joint Computer Aided Acquisition and Logistics Support (JCALS) system. One paper copy of DOS commercial technical manuals (operation/maintenance manuals) will be provided per unit. Manuals will have the ability to be updated as required.	

ANNEX A
RATIONALE ANNEX
TO THE
OPERATIONAL REQUIREMENTS DOCUMENT
FOR A
DEPLOYABLE OXYGEN SYSTEM (DOS)

4a(2)(a) Decreased barometric pressure at altitude and the resulting potential for hypoxic conditions in this environment require that oxygen purity will meet the required purity for therapeutic medical grade oxygen.

4a(2)(b) A larger LOX storage vessel provides an improved capability over the current LOX storage vessel. The new LOX storage vessel requires a delivery of gaseous oxygen to support the current Impact 754 Ventilator. With increased flow rate additional oxygen outlets can be provided to support more patients simultaneously.

4a(2)(c) Required oxygen generation rates and pressures for this system are intended to meet the requirements to drive existing gas-driven medical equipment. Flow rates are required to accomplish patient resuscitation procedures. Minimum flow rates of 11 LPM are further supported by American Heart Association cardiac life support guidelines, which require oxygen, be delivered at flow rates greater than 10 LPM.

4a(2)(d) The oxygen liquifier will eliminate current dependence on flight line supported LOX plants. The oxygen liquifier is intended to provide the capability to fill the LOX storage vessel, not to provide therapeutic oxygen directly to a patient.

4a(2)(e) The gaseous oxygen generator must be capable of sustaining patients during power outage condition.

4a(2)(f) In order to support ground operations, the LOX storage vessel must fit into these vehicles.

4a(2)(g) The DOS system is incorporated into the ground based medical assemblage for casualty care.

4a(2)(h) The LOX storage vessel is the portable oxygen supply used during patient transport and will accompany patients on aeromedical evacuation aircraft.

4a(2)(i) The DOS components must be man-portable to support ground and aeromedical operations and to meet transportability requirements.

4a(2)(j) Use in both ground and airborne operations and the wide variety of shipping modes available dictates that the DOS survive transport and be able to operate after and while being subjected to vibration and shock encountered during air, sea, and ground transportation.

4a(2)(k) Potential for worldwide deployment, staging, and use require the DOS be capable of operating under all environmental conditions.

4a(2)(l) Potential for worldwide deployment, staging, and use require the DOS be capable of operating under all environmental conditions.

4a(2)(m) Potential for worldwide deployment and staging require the DOS be capable of operating following exposure to all environmental storage conditions.

4a(3)(a) The DOS does not require aircraft power.

4a(3)(b) To support AE deployment into intra/inter theater operations, the DOS must be transportable on multiple AE aircraft. Use of the DOS on these multiple airframes requires a simple securing procedure to accommodate all possible configurations.

4a(3)(c) The FDA requires certification for development, production, and maintenance of any medical oxygen system.

4a(3)(d) The LOX storage vessel must be capable of operating at altitudes up to 15,000 feet to support both fixed and rotary wing patient airlift requirements.

4a(3)(e) The potential for loss of cabin pressurization dictates that the LOX storage vessel operate safely during and after cabin decompression without presenting a hazard to patient, crew, or aircraft operation. The other DOS components may be transported by aircraft and will operate after a decompression.

4a(4)(a) In order to support AE ground based operations, the DOS must be compatible with bare base power grid system and other worldwide deployable locations.

4c The majority of DOS units will be warehoused, as a War Reserve Materiel (WRM) item and must be capable of surviving long-term storage in all environmental conditions.

4c(1) To enhance system sustainment and support capabilities and improve reliability and performance, the DOS must be designed to meet the specified system life cycle.

4c(1) Oxygen is an important component of casualty care and must be reliable and easily maintainable.

4d(1) Aircraft and DOS safety considerations dictate that the DOS must operate in such a manner that the DOS will not affect nor be affected by aircraft flight control, navigation, or communications systems.

4d(2)(c) Potential for worldwide deployment, staging, and use require the DOS be capable of operating under all environmental conditions. As medical equipment it is subject to body fluid contamination and must be disinfected. The DOS must be capable of being disposed of safely without affecting the environment.

4d(5) Because the DOS draws ambient air in to generate oxygen (gaseous/liquid), any nuclear, biological or chemical contamination could render the DOS unusable. Market research indicates molecular sieve material may mitigate this risk. Further program testing is required.

4d(6) DOS shall not present a safety hazard to personnel, patients, facilities and aircraft when effected by bullets or conventional sympathetic detonations, while in operational or non-operational status.